

VALIDATION RESULTS FOR METHOD NO. MP-NIPM-MA					
		MEAN	RELATIVE STD. DEV. (%)	RANGE	SEE (conc)
ANALYTE MATRIX	NNAL Human urine				
DATE	14.Sept.01				
LLOQ	0.6 ng/100 mL Accuracy 71.7% RSD 35.0%				
STANDARD ERROR OF ESTIMATE OF QC SAMPLES (concentration units) (SEE = S.D./SQRT (# of determinations))	0.6 ng/100 mL 75 ng/100 mL 200 ng/100 mL	Low QC Med QC High QC			0.18 3.62 9.58
DESCRIPTIVE INFORMATION ON INSTRUMENT RESPONSE					
Function (Linear, Quadratic, etc.)	Linear				
Slope (mean)	18.53				
Intercept (mean)	0.08				
Other (mean regression value)	0.99679(1/y weighted)				
RECOVERY (as a %)					
High QC in (matrix)= Med QC in (matrix)= Low QC in (matrix)=	200 ng/100 mL 75 ng/100 mL 1.8 ng/100 mL	71.4% 81.8% 116.1%	Calculated as a % of the concentration observed for derivatized urine standards		
Results with different sample amounts (results of QC evaluations) intra-assay					
LLOQ QC=	0.6 ng/100 mL	0.43	35.0%	0.24-0.58	0.06
Low QC=	1.8 ng/100 mL	1.34	6.6%	1.23-1.47	0.04
Med QC=	75 ng/100 mL	70.03	7.5%	64.85-77.56	2.14
High QC=	200 ng/100 mL	179.46	8.4%	158.48-196.94	6.12
Results with different sample amounts (results of QC evaluations) inter-assay					
LLOQ QC=	n/a	n/a	n/a	n/a	n/a
Low QC=	1.8 ng/100 mL	1.8	35.0%	1.23-3.83	0.16
Med QC=	75 ng/100 mL	84.2	18.2%	64.85-120.54	3.62
High QC=	200 ng/100 mL	215.6	18.9%	158.48-309.65	9.58
STABILITY (assuming any degradation is linear):					
a) Room Temperature in Matrix (+/- %/24 hrs)	-18.4	% maximum			
b) Freeze/thaw (+/- %/3 cycles)	-19.7	% maximum			
c) Injector (+/- %/24 hrs)	-31.5	% maximum			

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